

REMARKS

Applicants would like to thank Examiner Miller for the personal interview with Applicants' representatives on August 4, 2004. As reflected in the Interview Summary, an agreement was reached that the amendments submitted herein overcome the art previously of record. Accompanying this Amendment, Applicants are filing a second Request for Continued Examination due to the Examiner's desire to update her search for thoroughness in view of these claim amendments.

Claims 1-3 and 21-24 remain in this application. Claims 1, 3 and 22-24 have been amended. No new matter has been added. Applicants respectfully request reconsideration in view of the above amendments and the following remarks.

Applicants' Response to Rejection under 35 U.S.C. §112

Claim 22 is rejected under 35 U.S.C. §112, first paragraph, as allegedly failing to comply with the written description requirement. Applicants respectfully traverse this rejection.

The Examiner alleges that siloxane is not disclosed to be in a particulate form and that there is no disclosure found combining an IPN having particles. The Examiner admits, however, that a particulate form is disclosed for other extractable polymers.

Applicants' respectfully submit that general disclosure appearing on pages 8 and 9 of the specification as originally filed supports the particulate form of siloxane, which is an extractable polymeric component, in an IPN with PTFE. As such, Applicants respectfully request reconsideration and withdrawal of the Section 112 rejection.

Applicants' Response to 35 U.S.C. §102 Rejection over Mitchell

Claims 1, 3, 21 and 24 are rejected under 35 U.S.C. §102(b) as allegedly being

anticipated by U.S. Patent No. 4,764,560 to Mitchell (hereinafter "Mitchell"). Applicants respectfully traverse the rejection on the basis that Mitchell fails to disclose each and every element of Applicants' claims, as amended herein.

The Examiner contends that Mitchell discloses a medical device, specifically a vascular graft, which is a tubular extrudate. The Examiner further contends that the tubular extrudate is an IPN of non-expanded PTFE having discrete domains of an extractable polymeric material. According to the Examiner, Mitchell teaches that the polymer is extracted from the PTFE matrix and will thereby create pores in the tubular extrudate. In particular, the Examiner specifically cites Table 5 in the Examples section in which extraction experiments were performed to determine the level of curing, or crosslinking, exhibited by silicone in the IPN.

Applicants have amended claims 1 and 3 herein to recite that the tubular extrudate is implantable. Applicants also have amended claims 1, 3 and 24 to require that the pores created in the non-expanded PTFE extrudate permit tissue ingrowth upon implantation. Support for these amendments is found on pages 1 and 12 of the specification as filed. Applicants' final product is a porous, non-expanded PTFE device for implantation in the body. The porous characteristic allows for sufficient tissue ingrowth when implanted in the body, which is largely accepted in the medical community as allowing assimilation of the implant in the body.

In contrast, the final product of Mitchell is an IPN of PTFE and silicone. Mitchell teaches expansion of this final product to create a porous microstructure, i.e., PTFE having a node and fibril structure. According to Mitchell, such material is achieved by stretching the PTFE to create a porous structure while simultaneously curing silicone. The silicone is an integral part of the final product. Mitchell merely teaches extraction experiments to determine the level of curing, or crosslinking, of the silicone in its final IPN product. Mitchell, however, does not teach or even suggest implantation in the body of a product in which the silicone has been extracted. Moreover, nowhere in Mitchell is it disclosed, taught or suggested that the

extracted silicone creates pores sufficient to permit tissue ingrowth. Therefore, Mitchell fails to disclose, teach or suggest each and every element recited in Applicants' amended claims.

It is well settled that to be an effective anticipatory reference, a cited document must disclose each and every limitation recited in a claim under examination. Failing such precise disclosure, such a cited document must fail as an anticipatory reference.

Therefore, Mitchell does not anticipate Applicants' amended claims 1, 3 and 24, or claim 21 which depends from claim 1 and thus contains all of the limitations of that claim. Applicants respectfully request reconsideration and withdrawal of this Section 102 rejection.

Applicants' Response to 35 U.S.C. §102 Rejection over Landi

Claims 23-24 are rejected under 35 U.S.C. §102(b) as allegedly being anticipated by U.S. Patent No. 5,141,522 to Landi (hereinafter "Landi"). Applicants respectfully traverse the rejection on the basis that Landi fails to disclose each and every element of Applicants' claims, as amended herein.

The Examiner contends that Landi discloses an implantable, tubular extrudate comprising a non-expanded PTFE matrix and a plurality of pores distributed throughout the matrix having a shape defined by an extractable polymeric material.

Contrary to the Examiner's allegations, Landi only discloses expanded PTFE. In particular, Landi discloses PTFE having a "fibrillar" structure, that is PTFE characterized by nodes and fibrils. Such PTFE is referred to as expanded PTFE. In contrast, Applicants' claims are directed to non-expanded PTFE. Applicants have amended claims 23 and 24 herein to specifically recite that the non-expanded PTFE has "no node and fibril structure." Nowhere in Landi is it disclosed, taught or suggested to use PTFE having no node and fibril structure. As such, Landi fails to anticipate claims 23 and 24, as further amended herein.

In view of the above, Applicants respectfully request reconsideration and withdrawal of this Section 102 rejection.

Applicants' Response to 35 U.S.C. §102 Rejection over Zilla

Claims 23-24 are rejected under 35 U.S.C. §102(e) as allegedly being anticipated by U.S. Patent No. 6,540,780 to Zilla et al. (hereinafter "Zilla"). Applicants respectfully traverse the rejection on the basis that Zilla fails to disclose each and every element of Applicants' claims, as amended herein.

The Examiner contends that Zilla discloses an implantable extrudate. With respect to claim 23, the Examiner contends that the implantable extrudate comprises a non-expanded PTFE matrix and a plurality of pores distributed throughout the PTFE matrix having a shape defined by an extracted polymeric material. With respect to claim 24, the Examiner alleges that the implantable extrudate comprises a non-expanded PTFE resin and a polymeric component, which is incompatible with the PTFE resin, wherein discrete domains of the polymeric component are distributed throughout the PTFE resin and are extractable therefrom.

Zilla discloses a graft made from thermoplastic elastomers, preferably polyurethanes. Helical channels are formed in the polyurethane graft by including extractable fibers in the graft material. The extraction of the fibers creates channels, or voids, in the polyurethane graft material itself. Although Zilla discloses the addition of non-extractable fibers, such as PTFE, these fibers are added to the polyurethane graft for reinforcement. These are PTFE fibers distributed in the polyurethane graft material, separate from the extractable fibers distributed in the polyurethane graft material. Accordingly, the extractable fibers are not distributed throughout the PTFE fibers. The extractable fibers are not extracted from the PTFE, nor do they create pores in the PTFE. Rather, the extractable fibers create voids in the polyurethane graft material.

In contrast, Applicants' amended claim 23 requires pores that are distributed throughout the non-expanded PTFE itself. Amended claim 24 requires domains of the polymeric component distributed throughout the non-expanded PTFE. Further, these domains must be extractable from the PTFE itself. Zilla fails to disclose, teach or suggest such recitations.

Accordingly, Zilla does not anticipate claims 23 and 24, as amended herein. Applicants respectfully request reconsideration and withdrawal of this Section 102 rejection.

Applicants' Response to 35 U.S.C. §102 Rejection over Pinchuk

Claim 23 is rejected under 35 U.S.C. §102(b) as allegedly being anticipated by U.S. Patent No. 4,657,544 to Pinchuk (hereinafter "Pinchuk"). Applicants respectfully traverse the rejection on the basis that Pinchuk fails to disclose each and every element of Applicants' claims, as amended herein.

The Examiner contends that Pinchuk discloses an implantable extrudate comprising a non-expanded PTFE matrix and a plurality of pores distributed throughout the matrix. The Examiner alleges that Pinchuk teaches extraction of salt from the matrix to create pores, and thus, Pinchuk's end product is the same as recited in Applicants' claims.

Applicants have amended claim 23 herein to include the recitation that the extractable polymeric material is in a gel, liquid or flowable form, as supported by disclosure on page 9 of the specification as filed. As such, the pores of Applicants' claimed implantable extrudate have a shape defined by the gel, liquid or flowable form of a polymeric material. This is in contrast to Pinchuk's pores, which have a shape defined by particulate salt crystals. Nowhere in Pinchuk is it disclosed, taught or suggested to create pores in non-expanded PTFE having a shape defined by a gel, liquid or flowable form of a material. As such, Pinchuk fails to anticipate Applicants' amended claim 23.

In view of the above, Applicants respectfully request reconsideration and withdrawal of this Section 102 rejection.

Applicants' Response to 35 U.S.C. §103 Rejection over Mitchell in view of Dereume

Claim 2 is rejected under 35 U.S.C. §103(a) as allegedly being obvious over Mitchell in view of U.S. Patent No. 5,639,278 to Dereume et al. (hereinafter "Dereume"). Applicants respectfully traverse the rejection.

In addressing Mitchell as a §102 reference, Applicants have already described in detail that Mitchell does not provide nor even suggest an implantable tubular extrudate of non-expanded PTFE having pores created by an extracted polymeric material. Further, Mitchell fails to disclose or even suggest that such pores are sufficient to permit tissue ingrowth upon implantation. For the sake of brevity, Applicants will not repeat the discussion on Mitchell.

For the same reasons that Mitchell fails as a reference under 35 U.S.C. §102, the combination of Mitchell and Dereume fail as a proper combination under 35 U.S.C. §103. Dereume is cited only for its teachings of combining a stent and a graft together and fails to teach or suggest anything of any relevance to the present invention as recited in the amended claims. Dereume clearly fails to cure the deficiencies of Mitchell. The combination of Mitchell and Dereume therefore fails to disclose each and every element of the claimed invention.

Withdrawal and reconsideration of the rejection is therefore respectfully requested.

Applicants' Response to 35 U.S.C. §103 Rejection over Mitchell

Claim 22 is rejected under 35 U.S.C. §103(a) as allegedly being obvious over Mitchell. Applicants respectfully traverse the rejection on the basis that Mitchell fails to suggest each and every element of Applicants' claim, as amended herein.

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As in claims 1, 3 and 24, Applicants have amended claim 22 to recite that the pores in the non-expanded PTFE extrudate permit tissue ingrowth upon implantation. In similarly addressing Mitchell as a §102 reference, Applicants have already described in detail that Mitchell's use of PTFE for his final product is only in the expanded form in combination with silicone. Mitchell does not create pores through extraction for use in an implant. Mitchell's pores in the final product are due to the use of expanded PTFE. There is no teaching or suggestion for additional pores created through extraction in Mitchell's final product. Further, Mitchell fails to provide or suggest that such pores are sufficient to permit tissue ingrowth. Therefore, Mitchell fails to suggest each and every element of Applicants' amended claim, and withdrawal and reconsideration of this rejection is respectfully requested.

In view of the foregoing, Claims 1-3 and 21-24 are now believed to be in proper form for allowance. A favorable reconsideration of the application on the merits is earnestly solicited.

If the Examiner has any questions regarding this Response, she is encouraged to contact the undersigned attorney.

Respectfully submitted,



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